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ABSTRACTS

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Randomized Phase 3 Study of Panitumumab With FOLFIRI vs. FOLFIRI Alone as Second-Line Treatment in Patients With Metastatic Colorectal Cancer

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Background: Panitumumab is a fully human anti-epidermal growth factor receptor monoclonal antibody approved as monotherapy for patients with metastatic colorectal cancer. The 181 study was designed to evaluate the efficacy and safety of panitumumab with FOLFIRI vs. FOLFIRI alone as second-line treatment for metastatic colorectal cancer according to tumor *KRAS* mutational status.

Methods: This was a randomized, multicenter, phase 3 study. Patients were randomized 1:1 to receive panitumumab 6.0 mg/kg Q2W+FOLFIRI vs. FOLFIRI alone. Patients had metastatic adenocarcinoma of the colon or rectum; only 1 previous chemotherapy regimen for mCRC; ECOG 0-2; and available tumor tissue for biomarker testing. Randomization was stratified by ECOG 0-1 vs. 2, previous oxaliplatin, and previous bevacizumab exposure. The co-primary end points were progression-free survival and overall survival and were independently tested. Originally designed to compare the treatment effect in the all-randomized population, the study was amended to focus on hypothesis testing in the wild-type *KRAS* subset. *KRAS* status was determined by a blinded central laboratory using allele-specific PCR prior to the first efficacy analysis.

Results: From June 2006 to March 2008, a total of 1,186 patients were randomized, signed informed consent, and received treatment. Overall demographics included 61% men, median (range) age 61 years (28-86), 48% ECOG 0, 45% ECOG 1. 1083/1186 pts (91%) had available tumor sample results for *KRAS*: 597 (55%) wild-type, 486 (45%) mutant. Preliminarily, across both arms, the most common grade 3 or 4

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adverse events were neutropenia (19%), diarrhea (12%), rash (8%), fatigue (6%), and dermatitis acneiform (4%).

Conclusions: Efficacy and safety data will be presented by *KRAS* status and treatment arm.